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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/355,793	09/21/1999	MARTIN BLASER	D5979	6942
27851	7590	12/29/2003	EXAMINER	
BENJAMIN A. ADLER 8011 CANDLE LANE HOUSTON, TX 77071			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/355,793

Applicant(s)

BLASER ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10/6/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,5,8-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,5,8-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 2-4, 6-7, 14 and 18 have been canceled.

Claims 1,5, 8-9,10-13,15-17 have been amended and are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections Withdrawn

2. This application now contains an abstract and meets the requirement set forth by 37 CFR 1.72(b).

3. Claims 7, 12, 15, 16 and 17^{are} objected to because of the following informalities in light of the cancellation of claim 7 and the amendments submitted to claims 12, 15 and 17.

4. Claims 6, 7, 11, 13 and 18^{are} rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the cancellation of claims 6-7 and 18 and amendment of claims 11 and 13 to recite a combination of new claim limitations (--further comprising--, and to depend from claim 11, respectively, that address the issues raised in the last office action.

5. Claims 1, 7, 9 and 18^{are} rejected under 35 U.S.C. 112, first paragraph (New Matter), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, in light of the cancellation of claims 7 and 18.

Objections and Rejections Maintained

6. Applicant states that "drawing corrections" were submitted, but no drawing corrections were received by the Office with the instant response. The need drawing corrections is still outstanding.

7. Claims 1, 5, 8^{are} rejected under 35 U.S.C. 102(b) as being anticipated by Dworkin et al (1995, J. Biological Chemistry, Vol. 270).

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8. Claims 1, 5, 8-13, 15-17^{are} rejected under 35 U.S.C. § 112, first paragraph (Deposit), for the reasons set forth in the objection to the specification, for reasons of record in paper number 6 and paper number 16.

9. Claims 1, 5, 8-13, 15-17^{are} rejected under 35 U.S.C. 112, first paragraph (*written description rejection*), in light of the amendment of the claims to recite the phrase "one or more" sapA homologs without any upper limit nor defined by a reference strain that comprises the plurality of sapA homolog coding sequences which read on SapCDEF, in addition to other sapA homolog coding sequences not described, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in paper number 13, paragraph 30 and paper number 16.

Response to Arguments

10. The rejection of Claims 1, 5, 8-13, 15-17 under 35 U.S.C. § 112, first paragraph (Deposit) rejection is traversed on the grounds that the claims have been amended to recite deposited strains and vectors that comprise the critical coding sequence and plasmids that contain the coding sequence for the sequences for the claimed invention, thus enabling the derived strains and methods of use.

11. It is the position of the examiner that the claims do not positively recite the Deposited strains and the coding sequences contained therein. The deposited strains are set forth in "()", and defines a term analogous to "such as". The amended claims have been newly rejected under 35 USC 112, second paragraph (see below). Amendment of the claims to positively recite the ATCC deposited strains could obviate this rejection.

12. The rejection of claims 1, 5-13, 15-18 under 35 U.S.C. 112, first paragraph (*written description*) is traversed by stating that "Applicants submit that is clear to one of ordinary skill in the art that sapB, sapC, sapD, sapE and sapF are not sapA homologs".

13. The examiner partially agrees with Applicant's arguments in so far as the claims have been amended to recite strain 23D and plasmid pIR100, but these claims do not positively recite the deposited strains and plasmids used to argue this rejection, as the coding sequences for sapCDEF and recA for C. fetus were not known at the time of filing, the instant specification

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does not disclose what the specific sequences are, and the claims do not positively recite the Deposited strains, as they are set forth in “()”. See Deposit rejection maintained above. The rejection could be obviated through amendment of the claims to positively recite the Deposited strains and plasmids used to traverse this rejection. Applicant’s arguments are not commensurate in scope with the instantly claimed invention.

14. The rejection of claims 1, 5, 8 under 35 U.S.C. 102(b) as being anticipated by Dworkin et al (1995, J. Biological Chemistry, Vol. 270) is traversed on the grounds that the claimed invention is directed to a “genetically engineered mutant C.fetus strain derived from strain 23D”.

15. It is the position of the examiner that strain 23D and 82-40 LP3 are both serotype A Campylobacter fetus strains of bacteria (see Table 1, page 15094), and express a 97 kDa SLP protein. Strain 82-40 LP3 can be considered to be a Campylobacter fetus strain derivative of strain 23 D as it differs from strain 23 D by expressing an additional antigen that is heterologous to strain 23D, specifically an 127 kDa SLP protein. Additional evidence is provided by Dworkin et al that strain 82-40 LP3 is a strain that is a mutant strain of strain 23D through showing the presence of common genetic elements (see Figures 4, 5, 6 and 7), as well as the absence of a genetic element (see Figure 4, left panel).

Dworkin et al disclose the expression of a chimeric protein (see page 15100, col. 2, last paragraph, middle “S-layer genes are novel in that they present a biological system in which the encoded proteins are naturally chimeric across serotypes) comprising the heterologous surface associated proteins in the S-layer (see Table 1 legend, page 15094) of an animal pathogen (Campylobacter fetus; instant claim limitations set forth in claim 5), wherein the protein is an antigen (. instant claim limitations set forth in claim 8).

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V

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IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

New Claim Limitations/ New Grounds of Objection/Rejection

Claim Rejections - 35 U.S.C. § 112

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 11, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 is directed to a method of immunizing a host by administering a mutant strain that comprises a heterologous coding sequence for a heterologous protein, the strain being defined to be the mutant strain of claim 11, but claim 11 is directed to a mutant strain with a heterologous protein sequence inserted into the only sapA coding sequence, thus disrupting the over all coding/reading frame of the DNA for the sapA encoded protein.

With disruption only expressed sapA homolog in the strain of claim 11 and claim 12, no surface chimeric protein would be produced, as the sapA protein would not be expressed due introduction of a frame shift, a possible stop codon being introduced, and/or the amino acids encoded would not result in the production of a sapA protein. Without expression of a sapA protein, the encoded protein would not be surface expressed, and no immune response induced to

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the heterologous protein as no sapA/heterologous protein would be produced. The claimed invention is not enabled for the induction of an immune response to an heterologous protein not expressed by the mutant strain of claim 11.

The mutant nucleic acid molecule would not encode a surface expressed sapA protein chimera together with a heterologous protein, because insertion of a heterologous protein into the only functional sapA homolog coding sequence as defined in independent claim 10, would disrupt and introduce a frame shift in the sapA homolog and not conserve the reading frame of the heterologous protein either. The claimed method of immunizing is not enabled, as no heterologous protein would be expressed as a surface chimera, because the only functional sapA homolog would be disrupted. The only functioning sapA homolog that could be expressed is mutated through insertion and disruption by a heterologous coding sequence. The claimed mutant strains are not enabled for expression of a heterologous or plurality of heterologous proteins when the only sapA homolog sequence that could be expressed prior to insertion of the heterologous coding sequence would result in a disrupted sapA coding sequence that would not express a surface associated heterologous protein, due to a frame shift, incomplete protein or incorrect three dimensional structure being produced from the insertional mutation introduced through the insertion of the heterologous coding sequence. Insertion of the heterologous coding sequence into the only functioning sapA coding sequence would result in a non-functional sapA homolog that would not be expressed in the mutant strain. The invention is not enabled for what is now claimed.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 1, 10, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10 and 12 have been amended to recite the terms “(PTA-4754)” and “(PTA-4753)”, respectively. It is not clear whether the claim limitations set apart by parenthetical notations are intended to be positively recited claim limitations. The claim is indefinite as it is unclear what the meets and bounds of the claim are, as the term(s) is/are set apart from the rest of the claim limitations as a possible example analogous to the recitation of “such as”. The claimed invention is not distinctly claimed.

Claim 11 depends from amended claim 10 and recites the phrase “a DNA cassette inserted into the coding sequence of a sapA homolog of said strain, and said DNA cassette encodes a heterologous protein, and expression of said DNA cassette results in surface expression of a chimeric protein comprising said heterologous protein.” As the strains of mutant *Campylobacter fetus* of claim 10 only “expresses only one S-layer protein encoded by one sapA homolog” and the coding sequence for the heterologous protein is inserted into the coding sequence for the sapA homolog, how will a sapA protein be expressed when the coding sequence of the sapA protein has been interrupted by the coding sequence of the heterologous protein. How or where the heterologous protein is inserted into the only sapA homolog that is functional in the mutant strain of independent claim 10, is not distinctly claimed, as an insertion of a complete coding sequence of a heterologous protein would not necessarily permit the expression of the sapA homolog S-layer protein, and disruption of the sapA protein would result in no surface expression of a chimeric protein. The invention is not distinctly claimed as it is not clear how surface expression would occur when only surface associated sapA coding sequence is functioning, and is interrupted by the heterologous coding sequence of claim 11.

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Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

December 18, 2003


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